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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,161	11/15/2001	Karl Tryggvason	TRV 20010-1-1-3	1993

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EXAMINER	
GUZO, DAVID	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SAM

Office Action Summary	Application No.	Applicant(s)	
	10/004,161	TRYGGVASON ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/01/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *12-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Applicant's election without traverse of Group I (Claims 1-11) in Paper No. 1 is acknowledged.

Claims 12-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 1 (received 12/1/03).

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). Specifically, non-initialed alterations have been made to the mailing address of inventor Parpala-Sparman and to the spelling of the name of inventor Pirkko Kortteinen.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,871,464 (hereafter the '464 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite the same method for delivery of a viral vector gene therapy pharmaceutical to a mammalian organ. Instant claims 1-3 and 5 are generic to all that is recited in claims 1-3 of the '464 patent, in other words, instant claims 1-3 and 5 are anticipated by claims 1-3 of the '464 patent. Specifically, the instant claims read generically on a method for delivering a viral vector gene therapy pharmaceutical to any mammalian organ while the claims in the '464 patent recite the same method for delivering a viral vector pharmaceutical to a kidney (which is a mammalian organ).

With regard to instant claim 4, wherein the method is practiced *in vitro*, since the *ex vivo* embodiment recited in the '464 patent encompasses an *in vitro* environment (because the cells are removed from a animal and need to be placed, for a time period, *in vitro* for the method to be used to deliver the viral vector), it must be considered that the *ex vivo* embodiment recited in the '464 claims reads on practicing the invention when the tissue or organ is *in vitro*.

With regard to claim 6, wherein the viral vector is recited as having a promoter and expression gene, it must be considered that for a viral vector to be gene therapy vector it must possess a gene to be expressed (transgene) and the wherewithal for the gene to be expressed (i.e. a promoter, polyadenylation or termination sequence, etc. operably linked to said gene) otherwise it is unclear how the vector would function as a

gene therapy pharmaceutical agent. Therefore, it must be considered obvious that the ordinary skilled artisan would include an expression gene and a promoter in any viral vector gene therapy pharmaceutical to be delivered to a target organ. On of ordinary skill in the art would have been motivated to include an expression gene and a promoter in a gene therapy vector because without said components, it is unclear how the vector could function as a gene therapy vector.

Claims 1-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 6-9 and 13 of U.S. Patent No. 6,342,214 (hereafter the '214 patent) in view of Bohinski et al. (U.S. Patent 5,976,873).

The '214 patent claims the same method for delivery of viral vectors to a target mammalian organ with the exceptions that the instant claims recite the viral vectors as being gene therapy vectors (having an expression gene and a promoter) and instant claims 7-11 recite that the target organ is specifically the lung. However, it would have been obvious for the ordinary skilled artisan to use the viral vectors recited in the '214 patent as gene therapy vectors and specifically use said vectors as gene therapy vectors for delivery to the lung because Bohinski et al. (see whole document, particularly columns 7-12) recites that gene therapy vectors (such as adenoviral or retroviral vectors comprising a transgene and promoter) can be used to deliver transgenes encoding therapeutic proteins (CFTR, superoxide dismutases, clotting factors, cytokines, etc.) to the lung to potentially treat patients for various diseases. It

would have been obvious for the ordinary skilled artisan, seeking to choose a type of viral vector to deliver to a target organ in a mammal, to chose a gene therapy viral vector for delivery to the lung because Bohinski et al. teaches that said vectors can be used to potentially treat diseases of the lung (or affecting the lung) in mammals. The ordinary skilled artisan would have been motivated to do this because Bohinski et al. teaches that delivery of gene therapy viral vectors to the lung is desirable because they can be used to potentially treat various diseases of the lung. Given the teachings of the claims in the '214 patent and the teachings of the prior art and the level of skill of said ordinary skilled artisan at the time the instant invention was made, said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claims 1-6 are directed to an invention not patentably distinct from claims 1-3 of commonly assigned 5,871,464. Specifically, the claims are not patentably distinct for the reasons cited in the above obviousness type double patenting rejection.

Claims 1-11 are directed to an invention not patentably distinct from claims 1-2, 6-9 and 13 of commonly assigned 6,342,214. Specifically, the claims are not patentably distinct for the reasons cited in the above obviousness type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Each of commonly assigned U.S. Patents 6,342,214 and 5,871,464, discussed above, would form the basis for a rejection of the noted claims under 35

U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 11 are vague in the recitation of "...further comprising providing a viral vector gene therapy pharmaceutical having a promoter and an expression gene." because it is unclear if this viral vector is the same as, or different from, the viral vector recited in claims 1 and 7. If the viral vector recited in claims 6 and 11 is different from

the viral vector recited in the claims from which these claims depend, it is unclear at what point in the method for delivery of a viral vector to the target organ the additional viral vector is used.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
February 18, 2004

DAVID GUZO
PRIMARY EXAMINER